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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Kathryn F. Sykes and Stephen A. Johnston	Group Art Unit: UNKNOWN
Serial No.: UNASSIGNED	Examiner: UNKNOWN
Filed: Concurrently Herewith	Atty. Dkt. No.: UTSD:557USD2/MWB
For: LINEAR AND CIRCULAR EXPRESSION ELEMENTS	

PRELIMINARY AMENDMENT

Commissioner for Patents
Washington, D.C. 20231

Commissioner:

Please amend this application as follows:

In the Specification

At Page 1, please delete the word "Provisional" from the line reading "Provisional Application For Letters United States Patent."

At page 2, please delete the paragraph spanning lines 2-5.

At page 2, please insert the following paragraph at line 2:

--This is a divisional application of co-pending application Serial No. 09/535,366 filed March 24, 2000, which claims priority to U.S. Provisional Application Serial No. 60/125,864,

filed March 24, 1999 and U.S. Provisional Application Serial No. 60/127,22, filed March 31, 1999, each of which disclosures is specifically incorporated herein by reference in its entirety.--

At page 5, please amend the paragraph spanning lines 7-10 as follows:

The nucleic acid segment containing the ORF, putative ORF, or any other nucleic acid segment which is comprised in a LEE or CEE may be obtained from any of a variety of sources. For example, it may be obtained by PCR®, from a linear nucleic acid that is cut out of a plasmid, or obtained by synthesis.

In the Claims

Cancel claims 1-53 and 63-96, without prejudice, or disclaimer.

Please amend claims 54, 56 and 58-62, by replacing them with the following substitute claims:

54. (Amended) A method of screening for a biological response comprising:

a) obtaining a linear or circular expression element by a process comprising:
obtaining a DNA segment comprising an open reading frame;
in vitro linking the open reading frame to a promoter to create a linear or circular expression element; and

b) providing the linear or circular expression element to a cell under conditions conducive to expression of any product encoded for by the open reading frame, such that a biological response is produced in the cell.

56. (Amended) The method of claim 54, wherein the open reading frame is non-covalently linked to the promoter.

58. (Amended) The method of claim 54, wherein the linear or circular expression element is injected into the cell.

59. (Amended) The method of claim 54, wherein more than one type of linear or circular expression element is introduced to the cell.

60. (Amended) The method of claim 108, further defined as a method of producing antibodies.

61. (Amended) The method of claim 108, further defined as a method of vaccinating the animal.

62. (Amended) The method of claim 61, wherein the animal is a mammal.

Please add new claims 97-109 as follows:

-- 97. (New) The method of claim 54, wherein the DNA segment is obtained from a process involving chemical synthesis.

98. (New) The method of claim 54, wherein the linear or circular expression element further comprises a terminator linked to the open reading frame.

99. (New) The method of claim 98, wherein obtaining the expression element further comprises non-covalently linking a terminator to the open reading frame.

100. (New) The method of claim 98, wherein the terminator is a eukaryotic terminator.

101. (New) The method of claim 54, wherein the open reading frame is produced *in vivo* and then non-covalently linked to the promoter *in vitro*.

102. (New) The method of claim 54, wherein obtaining the expression element comprises polymerase chain reaction to produce the open reading frame.

103. (New) The method of claim 54, wherein obtaining the expression element comprises chemical synthesis of the open reading frame.

104. (New) The method of claim 54, wherein the promoter is a eukaryotic promoter.

105. (New) The method of claim 54, wherein after obtaining the linear or circular expression element, the linear or circular expression element is provided to the cell without intervening bacterial propagation or cloning.

106. (New) The method of claim 54, wherein the cell is in a tissue culture.

107. (New) The method of claim 54, wherein the cell is in an organism.

108. (New) The method of claim 107, wherein the cell is an animal.

109. (New) The method of claim 58, wherein the injection is performed using microprojectile bombardment.--

Appendix A contains the amended paragraph of page 5, lines 7-10 with appropriate editing indicia. Appendix B contains a clean copy of the added and edited parts of the specification as believed to exist after the amendments. Appendix C contains the amendments to the claims with appropriate editing indicia. Appendix D contains a copy of the pending claims, after editing of the amendments.

REMARKS

In the parent case, U. S. Serial No. 09/535,366, Applicants received a Restriction Requirement indicating that the claims as filed constituted eight separate inventions as follows: Group I, drawn to a method of assaying for the production or regulation of the expression of at least one polypeptide, classified in class 436, subclass 6, as exemplified by originally filed claims 1-27; Group II, drawn to a method of analyzing a nucleic acid sequence, classified in class 435, subclass 6, as exemplified by originally filed claims 28-39; Group III, drawn to a method of analyzing a nucleic acid sequence for activity as a promoter, classified in class 435,

subclass 6, as exemplified by originally filed claims 40-53; Group IV, drawn to a method of screening for a biological response classified in class 435, subclass 6, as exemplified by originally filed claims 54-62; Group V, drawn to the method of vaccinating an organism, classified in class 514, subclass 44, as exemplified by originally filed claims 63-74; Group VI, drawn to a method of selecting open reading frames effective for generating an immune response, classified in class 435, subclass 6, as exemplified by originally filed claims 75-79; Group VII, drawn to the method of producing a linear or circular expression vector, classified in class 435, subclass 91.1 and 91.2, as exemplified by originally filed claims 80-87; and Group VIII, drawn to a linear or circular expression vector, classified in class 435, subclass 320.1, and class 536, subclass 23.1, as exemplified by originally filed claims 88-96.

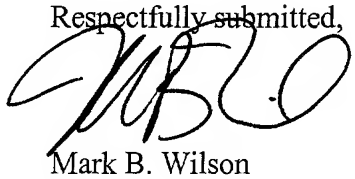
The Group VI invention was elected for prosecution in the parent case, which was allowed on January 17, 2000, but has not yet issued. Applicants have determined to elect to prosecute Group IV in the present case. Claims 1-53 and 63-96 have thus been canceled from this divisional application.

Therefore, the active claims in this case are claims 54-62 as amended in the Amendment above, and newly added claims 97-109, all as set forth in Appendix D.

The specification has been amended to recite the relationship with the parent case, and a correction of a minor typographical error at the first page and the fifth page.

It is believed that no fee is due; however, should any fees under 37 C.F.R. §§ 1.16 to 1.21 be required for any reason, the Commissioner is authorized to deduct said fees from Fulbright & Jaworski L.L.P. Account No.: 50-1212/10200689/MBW.

Respectfully submitted,



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Date: February 15, 2002

APPENDIX A:- COPY OF AMENDMENT TO SPECIFICATION WITH EDITING INDICIA

The paragraph at page 5, lines 7-10 has been amended as follows:

The [he] nucleic acid segment containing the ORF, putative ORF, or any other nucleic acid segment which is comprised in a LEE or CEE may be obtained from any of a variety of sources. For example, it may be obtained by PCR®, from a linear nucleic acid that is cut out of a plasmid, or obtained by synthesis.

APPENDIX B:- CLEAN COPY OF NEW/EDITED PORTIONS OF THE SPECIFICATION AFTER AMENDMENT

The following paragraph has been inserted at page 2, line 2:

This is a divisional application of co-pending application Serial No. 09/535,366 filed March 24, 2000, which claims priority to U.S. Provisional Application Serial No. 60/125,864, filed March 24, 1999 and U.S. Provisional Application Serial No. 60/127,22, filed March 31, 1999, each of which disclosures is specifically incorporated herein by reference in its entirety.

The paragraph at page 5, lines 7-10, as amended is as follows:

The nucleic acid segment containing the ORF, putative ORF, or any other nucleic acid segment which is comprised in a LEE or CEE may be obtained from any of a variety of sources. For example, it may be obtained by PCR®, from a linear nucleic acid that is cut out of a plasmid, or obtained by synthesis.

APPENDIX C:- MARKED COPY OF CLAIMS

54. (Amended) A method of screening for a biological response comprising:

a) obtaining a linear or circular expression element by a process comprising:
obtaining a DNA segment comprising an open reading frame;
in vitro linking the open reading frame to a promoter [and a terminator] to create a linear or circular expression element; and

b) providing the linear or circular expression element to a cell [an organism] under conditions conducive to expression of any product encoded for by the open reading frame, such that a biological response is produced in the cell.

56. (Amended) The method of claim 54, wherein the open reading frame is non-covalently linked to the promoter [and the terminator].

58. (Amended) The method of claim 54, wherein the linear or circular expression element is injected into the cell [organism].

59. (Amended) The method of claim 54, wherein more than one type of linear or circular expression element is introduced to the cell [organism].

60. (Amended) The method of claim 108 [54], further defined as a method of producing antibodies [for analytical purposes].

61. (Amended) The method of claim 108 [54], further defined as a method of vaccinating the animal [organism].

62. (Amended) The method of claim 61 [54], wherein the animal [organism] is a mammal [or plant].

97. (New) The method of claim 54, wherein the DNA segment is obtained from a process involving chemical synthesis.

98. (New) The method of claim 54, wherein the linear or circular expression element further comprises a terminator linked to the open reading frame.

99. (New) The method of claim 98, wherein obtaining the expression element further comprises non-covalently linking a terminator to the open reading frame.

100. (New) The method of claim 98, wherein the terminator is a eukaryotic terminator.

101. (New) The method of claim 54, wherein the open reading frame is produced *in vivo* and then non-covalently linked to the promoter *in vitro*.

102. (New) The method of claim 54, wherein obtaining the expression element comprises polymerase chain reaction to produce the open reading frame.

103. (New) The method of claim 54, wherein obtaining the expression element comprises chemical synthesis of the open reading frame.

104. (New) The method of claim 54, wherein the promoter is a eukaryotic promoter.

105. (New) The method of claim 54, wherein after obtaining the linear or circular expression element, the linear or circular expression element is provided to the cell without intervening bacterial propagation or cloning.

106. (New) The method of claim 54, wherein the cell is in a tissue culture.

107. (New) The method of claim 54, wherein the cell is in an organism.

108. (New) The method of claim 107, wherein the cell is an animal.

109. (New) The method of claim 58, wherein the injection is performed using microprojectile bombardment.

APPENDIX D: - COPY OF PENDING CLAIMS FOLLOWING AMENDMENT

54. A method of screening for a biological response comprising:

a) obtaining a linear or circular expression element by a process comprising:
obtaining a DNA segment comprising an open reading frame;
in vitro linking the open reading frame to a promoter to create a linear or circular expression element; and

b) providing the linear or circular expression element to a cell under conditions conducive to expression of any product encoded for by the open reading frame, such that a biological response is produced in the cell.

55. The method of claim 54, wherein the DNA segment is obtained from a process involving PCR®.

56. The method of claim 54, wherein the open reading frame is non-covalently linked to the promoter.

57. The method of claim 54, wherein the non-covalent linkage is performed by:

a) obtaining a PCR® product comprising the open reading frame, which PCR® product is obtained by amplification from at least one primer that has complementary stretches comprising deoxyuridines with uracil-DNA glycosylase to create overhangs to which the promoter and terminator can link;

b) providing a promoter and a terminator; and

c) non-covalently linking the promoter and the terminator to the open reading frame to create the linear or circular expression element.

58. The method of claim 54, wherein the linear or circular expression element is injected into the cell.

59. The method of claim 54, wherein more than one type of linear or circular expression element is introduced to the cell.

60. The method of claim 108, further defined as a method of producing antibodies.

61. The method of claim 108, further defined as a method of vaccinating the animal.

62. The method of claim 61, wherein the animal is a mammal.

97. The method of claim 54, wherein the DNA segment is obtained from a process involving chemical synthesis.

98. The method of claim 54, wherein the linear or circular expression element further comprises a terminator linked to the open reading frame.

99. The method of claim 98, wherein obtaining the expression element further comprises non-covalently linking a terminator to the open reading frame.

100. The method of claim 98, wherein the terminator is a eukaryotic terminator.

101. The method of claim 54, wherein the open reading frame is produced *in vivo* and then non-covalently linked to the promoter *in vitro*.

102. The method of claim 54, wherein obtaining the expression element comprises polymerase chain reaction to produce the open reading frame.

103. The method of claim 54, wherein obtaining the expression element comprises chemical synthesis of the open reading frame.

104. The method of claim 54, wherein the promoter is a eukaryotic promoter.

105. The method of claim 54, wherein after obtaining the linear or circular expression element, the linear or circular expression element is provided to the cell without intervening bacterial propagation or cloning.

106. The method of claim 54, wherein the cell is in a tissue culture.

107. The method of claim 54, wherein the cell is in an organism.

108. The method of claim 107, wherein the cell is an animal.

109. The method of claim 58, wherein the injection is performed using microprojectile bombardment.